K083687

510(K) SUMMARY

Submitted by:

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JUN 11 2009

Preparation Date: Jun. 10. 2008

Contact Person/Prepared by:

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510(K) Summary of Safety and Effectiveness for the:

Trade/Proprietary Name: BAIXIN™ Intravascular Administration Set

Common Name: INTRAVASCULAR ADMINISTRATION SET

Classification Name: set, administration, intravascular

Class: II

K083687

Procodes: FPA - set, administration, intravascular

Device Description:

BAIXIN™ Intravascular Administration Set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. This device is sterile and for single use only, so the following precautions shall be observed during use:

(1) Don't use when visual damage on its packaging is detected or the protective cap is found not in position.
(2) Only for single use, discard after use.
(3) Use before expiration date.
(4) It shall be used immediately after the individual package is opened.

Intended Use:

The intended use of the BAIXIN™ Intravascular Administration Set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

Statement to conform to ISO 8536-4-2007:

Anhui Kangda Medical Products Co., Ltd. has established that its family of syringes corm to the FDA recognized consensus standard, ISO 8536-4-2007, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed.* Data supporting conformance with the standard is available from Anhui Kangda Medical Products Co., Ltd.

Summary of Testing:

All materials used in the fabrication of the Anhui Kangda piston syringe and hypodermic needles were evaluated for:

Test items	Requirements
Sterility	No evidence of growth of BI
Pyrogenicity	Free from pyrogenicity (Bacterial endotoxin test)
Haemolysis	The infusion set shall be free from haemolytic reactions
Toxicity	Free from toxicity
Reducing (oxidizable) matter	The total amount of potassium permanganate solution used [c(KMnO4)=0.002mol/l]shall not exceed 2.0ml;
Metal ions	The extract shall not contain in total more than 1μg/ml of cadmium, chromium, copper, lead and tin.
	Not more than 0.1μg/ml of cadmium, when determined by atomic absorption spectroscopy (AAS) or equivalent method.
Titration acidity or alkalinity	Not more than 1ml of either standard volumetric solution shall be required for the

	indicator to change to the colour grey
Residue on evaporation	The total amount of dry residue shall not exceed 5 mg.
UV absorption of extract solution	The extract solution S, shall not show absorption greater than 0.1.
EO residue	Less than 0.5mg/set
Particulate contamination	Contamination index<90
Leakage	Immerse the infusion set, with one end blocked, in water at 20℃ to 30℃ and apply an internal air pressure of 50kPa above atmospheric pressure for 15s. Examine the infusion set for air leakage. Apply an internal excess pressure of -20kPa at (23±1)℃ and (40±1)℃ for 15s. inspect whether air enters the infusion set.
Tensile strength	Withstand a static tensile force of not less than 15N for 15s;
Closure-piercing device	Dimensions
	The closure-piercing device shall be capable of piercing and penetrating the closure without prepiercing. No coring should occur during this procedure.
Air-inlet device	The air-inlet device shall be provided with an air filter to prevent the ingress of microorganisms into the container
	Air went trough rate≥90%
	The air-inlet device shall be separate from, or integral with, the closure-piercing device.
	The air admitted into the container shall not become entrained in the liquid outflow.
	The flow rate of fluid is not reduced by more than 20% of that from a freely ventilated container.
Tubing	The tubing shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.
	The tubing length distal to the drip chamber shall be not less than 1500mm in length.
Fluid filter	The retention of latex particles on the filter shall be not less than 80%
Dimensions of the drip chamber	There shall be a distance of not less than 40mm between the drip tube and fluid filter
	The wall of the drip chamber shall not be closer than 5mm to the end of the drip tube
	The drip tube shall be such that 20 drops of distilled water

	or 60 drops of distilled water at 23±2℃ and at a flow rate of 60 drops/min±10drops/min deliver a volume of 1ml±0.1ml(1g±0.1g)
Flow regulator	The flow regulator shall adjust the flow of the infusion solution between zero and maximum.
	The regulation length should be no less than 30mm.
Flow rate	20 drops, 10min>1000ml
Injection port	There shall be no leakage of more than one falling drop of water.
Male conical fitting	In accordance with ISO594-1 or ISO594-2
Protective cap	The protective caps shall maintain the sterility of the closure-piercing device, the male conical fitting and the interior of the infusion set.
Individual package	The infusion set and/or the air-inlet device shall be individually packed so that they remain sterile during storage. The unit container shall be sealed in a tamper-evident manner.
no flattened portions and kinks.	The infusion set and/or the air-inlet devices shall be packed and sterilized in such a way that there are no flattened portions or kinks when they are ready for use.

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2009

Anhui Kangda Medical Products Company, Limited
C/O Mr. Bian Wei Qiang
Shanghai Carelife International Trading Company, Limited
1707 Yinqiao Building 58 Jinxin Road, Jinqiao
Pudong, Shanghai
CHINA 201206

Re: K083687
Trade/Device Name: BAIXIN™ Intravascular Administration Set (BAIXIN™)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 3, 2009
Received: June 3, 2009

Dear Mr. Qiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083687

Indications for Use

510(k) Number (if known): K083687

Device Name: BAIXIN™ Intravascular Administration Set (BAIXIN™)

Indications for Use: Intravascular Administration Set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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